

PHARMACEUTICALS IN VIETNAM MARKET

BRIEF NOTE



20
22



Ministero degli Affari Esteri
e della Cooperazione Internazionale

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ITALIAN TRADE AGENCY

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1. OVERVIEW ABOUT LOCAL MARKET

According to the General Statistics Office of Vietnam, the GDP growth rate of the country maintained over 6% since 2015 and even exceeded 7% in 2018 and 2019. In 2021, accompanied by China and Myanmar, Vietnam experienced a positive growth rate, at the same time the economy scale reached over 278 billion EUR, passed Singapore (273 billion EUR) and Malaysia (272 billion EUR). GDP in 2021 increased by 2.58% compared to the previous year because the Covid-19 epidemic has seriously affected all sectors of the economy, especially in the third quarter of 2021, many key economic localities have to implement social distancing measures to prevent the spread of the epidemic. While most manufacturing and trading industries faced difficulties due to rising input prices, the pharmaceutical industry has been less affected.

Vietnam has a relatively large market size with a population of over 98 million and an average life expectancy of approximately 76 years. As per the World Bank, the number of Vietnamese people aged 65 and over, reached 7.6 million in 2020 accounting for nearly 7.9 percent of the country's total population. The General Statistics Office (GSO) of Vietnam forecasts that the number will reach 18.1 percent by 2049. Around 30 percent of the Vietnamese population that can afford relatively expensive western medicine is growing.

According to a report by the Vietnam Social Insurance Agency, in 2010, only 60 percent of Vietnam's population had health insurance, while in 2019, this figure was up to 90 percent. Another driving force for the pharmaceutical industry is the rapid urbanization rate. Vietnam's urbanization rate was at 37 percent in 2020 and in 2021 the urban population stood at approximately 36.6 million.

Drugs are currently distributed mainly via ETC channel which accounts for over 60%. There are about 57,000 drugstores nationwide. The development of the ETC channel comes from the health insurance policy of the government which makes health insurance compulsory. In addition, private hospitals flourish and awareness of healthcare rises, while the living environment is increasingly at high risk of pollution, leading to more diseases, also lead to higher number of people going to hospitals. These factors contribute to the inevitable development of the pharmaceutical industry in Vietnam.

Imported drugs still dominate the market with a slight increase in market share from 56% in 2020 to 58% in 2021 (GSO), due to the fact that the domestic drug supplies hardly increase because of the stagnant progress of many domestic factories, along with the increased demand for Covid-specific drugs from foreign pharmaceutical companies.

Considering the aforementioned information, Vietnam proves to be an attractive market for Italian companies to make an entry or invest in the market.

When the EU-Vietnam Free Trade Agreement (EVFTA) comes into effect in 2020, new rates of tariff have been applied, enhancing the competitiveness of European products when entering the local market. Vietnamese enterprises will have to compete fairly with businesses from the EU. Vietnam will also align with international standards on pharmaceuticals which means that products already certified in the EU will not require additional testing and certification in Vietnam, thus reducing time and costs in the Vietnamese market. EU investors are now allowed to establish a company to import pharmaceutical products and sell to local distributors or wholesalers. They are also allowed to build warehouses and carry out clinical research and trials.

Below we are going to give brief analysis on pharmaceuticals – a prospective market in Vietnam for exporters and investors.

2. PHARMACEUTICAL MARKET

2.1 BRIEF ANALYSIS

According to the market research firm IBM, the Vietnamese pharmaceutical market in 2021 was worth around \$7.7 billion and is expected to reach \$16.1 billion by 2026.

As per SSI Research, demand for pharmaceutical products will continue to increase. In the first quarter of 2022, the total pharmaceutical revenue of Vietnam was estimated to increase by 7 per cent over the same period in 2021, of which the pharmacy channel increased by 23 per cent, and the hospital channel decreased by 5 per cent. The pharmaceutical industry's revenue in the last six months of 2022 is estimated to increase by about 13 per cent over the same period in 2021, so the figure for the whole year would be 11 per cent, recovering almost to the level before the appearance of COVID-19. The race to open new pharmacies of major drugstore chains such as Pharmacity, Long Châu and An Khang will stimulate the pharmaceutical industry's revenue to grow.

The pharmaceutical production and business system are expanding with about 250 manufacturing plants, 200 import-export facilities, 4,300 wholesale agents, and more than 62,000 retail agents. According to statistics of the Drug Administration of Vietnam (DAV), as of August 2019, Vietnam had approximately 184 pharmaceutical manufacturers operating in the market (both local and foreign companies) (of which, there are 225 manufacturing sites qualified

GMP-WHO). Major pharmaceutical companies in Vietnam are clustered in and around the capital Hanoi, Hai Duong province, Ho Chi Minh City, and some southwest provinces including Can Tho City and Dong Thap province.

According to KPMG's report in 2020, pharmaceutical expenditure per capita in Vietnam stood at 47 EUR in 2017 and is expected to reach 137 EUR by 2025.

Meanwhile, foreign pharmaceutical companies tend to conduct M&A to take advantage of available resources to reduce costs and shorten time to enter the Vietnamese market. The potential industry has attracted many foreign corporations such as Abbott (owned 51.7% shares of Domesco and acquired Glomed Pharmaceutical), Taisho (accounted for 50.78% of DHG Pharma's shares), Stada Service Holding B.V (approved to increase its ownership rate to a maximum of 72% in Pymepharco), Adamed Group (acquired 70% of Davipharm's shares), etc. Therefore, it is expected that there will be many M&A deals in the pharmaceutical sector in the coming years when the government plans to reduce the ownership rate in domestic pharmaceutical companies.

Domestically, the pharmaceutical industry has also attracted strategic investment of many local big groups such as Vingroup, FPT, Masan Group, Vinamilk, The Gioi Di Dong, Digiworld. Pharmaceutical retail chains or drugstores such as Pharmacy, Long Chau, An Khang, ECO Pharmaceuticals, My Chau Pharmacy, etc. are actively completing distribution system and expanding their business throughout the country.

According to statistics in Table 1, it can be figured out from the chart that the total export value of pharmaceutical products to Vietnam increased gradually from 2018 to 2020, in spite of the pandemic. As it can be seen clearly, in 2021, **Germany was the biggest supplier** with an export value of 464 million EUR. **Belgium came in 2nd place** when exporting 412.9 million EUR. **China ranked 3rd** in the list (over 398 million EUR) while **United States made it the 4th** biggest export country to Vietnam for 310 million EUR. The dramatic increase in export value of Chinese pharmaceutical products can be attributed to the high demand of Covid-19 vaccine when the pandemic hit Vietnam hard in 2021.

Table 1. Export of Pharmaceutical products to Vietnam from 2018 to 2021*(HS code 30^, FOB price, value in EUR)*

Countries		2018	2019	2020	2021	Var. 2020/21	Market share		
							2018	2019	2020
1	Germany	182,941,000	217,141,000	259,091,000	464,058,000	79%	9.77%	9.97%	11.57%
2	Belgium	100,942,640	159,821,454	239,856,447	412,949,494	72%	5.39%	7.34%	10.71%
3	China	67,587,017	55,087,025	54,577,593	398,341,474	630%	3.61%	2.53%	2.44%
4	United States	49,907,070	69,765,048	102,360,179	310,252,129	203%	2.66%	3.20%	4.57%
5	Others	1,471,823,948	1,676,678,478	1,582,675,283	1,571,345,566	-1%	78.57%	76.97%	70.70%
Total Value		1,873,201,675	2,178,493,005	2,238,560,502	3,156,946,663	41%	100%	100%	100%
Var.by Year		-4%	16%	3%	41%				

Source: ICE processing of Trade Data Monitor LLC

In 2021, Italy ranked 15th in supplying for Vietnam pharmaceutical market with an export value of 41.3 million EUR. Although the export value experienced a significant rise of 13.71% in 2019, it then suffered a slight decline in growth rate by 3.11% and 8.56% in 2020 and 2021, respectively. (illustrated in Table 2)

Table 2. Export of Pharmaceutical products from Italy to Vietnam 2018-2021*(HS code 30^, FOB price, value in EUR)*

	2018	2019	2020	2021
Export value from Italy	41,119,687	46,759,123	45,227,516	41,354,676
Growth rate	-8.07%	13.71%	-3.28%	-8.56%
Market share	2.20%	2.15%	2.02%	1.31%
Var.by Year	-4.49%	-2.22%	-5.87%	-35.16%

Source: ICE processing of Trade Data Monitor LLC

While the government has prioritized advancing its domestic pharmaceutical industry, the country's capabilities are still limited to generic medicines, simple dosage forms, and functional foods. Vietnam is also highly dependent on imported pharmaceutical materials, of which Chinese and Indian sources account for more than 85 percent. Unlike the Chinese and Indian markets, local competition for innovative and complex treatments is not a threat to new investors as even major domestic manufacturers are still small and medium in size with limited capital, R&D resources as well as supply chains. Therefore, with the right strategy, foreign pharmaceutical companies can benefit by involving in this early stage of the industry supply chains as there are yet to be large competitors in the market.

One of the key challenges for foreign pharmaceutical businesses operating in Vietnam is that FDI logistic companies and foreign pharmaceutical companies are not permitted to distribute pharmaceutical products directly and must sell their products to domestic pharmaceutical distributors. Furthermore, the distribution network is still fragmented, inefficient, and suffers from poor transparency.

Another challenge for MNCs operating in Vietnam is the potential delays in regulatory approval for new medicines. The Drug Administration of Vietnam remains the only branch of the Ministry of Health responsible for managing and approving market authorization, assessing GMP, and releasing business and product licenses.

Therefore, initial reviews can be expected to take up to a year, while clinical trials can take up to at least three years, and assessment of stability data adds another year. Such a lengthy regulatory procedure may undermine the competitiveness of any foreign pharmaceutical enterprise that aims for further approval for the US and European markets while making it more challenging for these companies to recoup the investment.

Advertising is another area that should be of concern to pharmaceutical businesses in Vietnam. Advertising of over-the-counter drugs is allowed in Vietnam, but the advertising of prescription drugs is illegal.

2.2 IMPORT DUTY

The rates in the Tab. 3 below are applied for pharmaceutical products imported from EU countries based on EVFTA.

Table 3. Vietnam Import Duty for Pharmaceuticals Imported from EU countries

(based on the EVFTA - European Union Vietnam Free Trade Agreement)

HS code	Description	Import duty 2022 (%)
30045010	Other, containing vitamins or other products of a kind suitable for children, in syrup form	0
30049030	Antiseptics	0
30049051	Analgesics, antipyretics and other medicaments for the treatment of coughs or colds, whether or not containing antihistamines: acetylsalicylic acid, paracetamol or dipyron (INN), of a kind taken orally	3.1
3005	Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes.	4.3
300610	Sterile surgical catgut, similar sterile suture materials (including sterile absorbable surgical or dental yarns) and sterile tissue adhesives for surgical wound closure; sterile laminaria and sterile laminaria tents; sterile absorbable surgical or dental haemostatics; sterile surgical or dental adhesion barriers, whether or not absorbable	0

2.3 REGISTRATION REGULATIONS

Circular No.32/2018/TT-BYT regulates the registration of circulation of drugs and medicinal ingredients, officially took effect from September 2019. According to the Ministry of Health, the provisions in this Circular follow the trend of international integration, ensuring the harmony with ASEAN and the World Health Organization.

Specifically, the validity period of a certificate of Marketing Authorization of drugs and medicinal ingredients is 5 years from the date of issuance or renewal. Particularly for some special cases, this certificate is valid for 3 years from the date of issuance:

Registration of generic drugs

Step 1: The applicant submits 01 dossier for a certificate of Marketing Authorization as prescribed in Article 28 of

Circular No.32/2018/TT-BYT to the Drug Administration of Vietnam (DAV) - Ministry of Health.

Step 2: Upon receipt of the application with sufficient documents following required format, and full fee (200 EUR), DAV will issue the application receipt to the applicant using the Form No. 12/TT attached to this Circular.

Step 3: Within 12 months from the date on the application receipt, DAV is responsible for:

- a) Organize the appraisal of registration dossiers;
- b) Submit to the Advisory Council for issuing, not issuing and requesting appraisal advice of Marketing Authorization certificates for the applications.
- c) Issue Marketing Authorization certificate according to the conclusions of the Advisory Council after approval of the leaders of the Ministry.

Step 4: In case the application is unsatisfactory or refused, within the time limit for considering the application for registration, DAV must send a written reply clearly stating the reason.

- Time for applicant to amend and supplement the dossiers:
 - No more than 36 months from the date of the written notification from DAV, for cases where preclinical, clinical, bioequivalence, and stability studies must be supplemented.
 - No more than 12 months from the date of the written notification from DAV for the remaining cases.

The time for the applicant to amend or supplement the dossier is not included in the time limit for considering the application. If exceeded, the registration dossier is no longer valid and the applicant must re-submit the registration.

Step 5: Additional documents are submitted online, by post or directly to DAV. The order of settlement shall be carried out from Step 1.

2.4. VIETNAM'S BIDDING AND GRADE SYSTEM

It takes about five years for a drug to enter the Vietnamese market after it has been developed, beginning with two and a half years of clinical trials, and then another two and a half years to receive approval from the government.

Vietnam uses a grading system to divide companies into different groups that decide how much they can be involved in bidding; a grade of 1 provides the most freedom and 5 the least.

- Grade 1:

- Countries that are part of the International Conference on Harmonization (ICH); or
 - Pharmaceutical companies that are based in Australia; or
 - Manufacturers certified by PIC/S GMP or EU GMP; or
 - Manufacturers that have won the World Health Organization's (WHO) GMP certification given by the Vietnamese government and sell their products to members of ICH.
- Grade 2: Companies must be part of the European Union CMP or certified with GMP by PIC/S.
 - Grade 3: Pharmaceutical producers who have achieved WHO's FMP awarded by the Vietnamese government.
 - Grade 4: The products must have gone through the bioequivalence
 - Grade 5: All other drugs.

3. CONCLUSIONS AND RECOMMENDATIONS

Vietnam is expected to open up promising business opportunities for future exporters as they can benefit from the following favorable conditions:

- Large market of over 97 million inhabitants with one of the fastest-growing middle classes in Asia. However, this newly-urbanized cohort is rapidly aging and at increasing risk of developing non-communicable diseases.
- Distribution system have improved with the joining of some retail chains such as Pharmacity, Long Chau, An Khang, ECO Pharmaceuticals, My Chau Pharmacy, etc., which expanded many branches throughout the country, mainly in Hanoi and Ho Chi Minh City.
- With the entry into force of the EVFTA, the import duties for pharmaceutical products will be eliminated immediately or reduced gradually to 0 after 6-11 years, depending on the types of products.

However, foreign companies can face some challenges due to the government's effort to stimulate local pharmaceutical manufacturers and the domestic producing ability. There are still some inadequacies in the management policy regarding pharmaceutical quality and price because it has not kept up with market fluctuations and is still in the process of improvement. Potential exporters or investors should research on the demand of the local market carefully and define suitable type of investment and strategy to make a successful entry into the market.

For any further information and request services, please contact ICE HCMC via e-mail: hochiminh@ice.it



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